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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,637	03/15/2002	Gerardo M. Castillo	PROTEO.P16CI	4148

7590 09/13/2006

PATRICK M. DWYER
PROTEOTECH, INC.
12040 115TH AVE., N.E.
KIRKLAND, WA 98034

EXAMINER	
WILLIAMS, LEONARD M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/099,637	CASTILLO ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on 6/19/06

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-15,17 and 19-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-15,17 and 19-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/19/2006 has been entered.

Status of Claims

The examiner notes the receipt of the applicant's remarks on 6/19/2006 amending claim 17 and presenting new claims 19-29. Claims 9-15, 17 and 19-29 are currently pending.

The rejections of the previous office action are hereby withdrawn due to applicant's amendment of the claims. New rejections covering the amended and new claims follow.

The obviousness-type double patenting rejections are maintained, as no terminal disclaimers have been filed.

Response to Arguments

Applicant's arguments filed 6/19/2006 have been fully considered but they are not persuasive.

The applicant's state on page 5 of the remarks: "The Examiner persistently has refused to credit our previous arguments." The examiner respectfully disagrees with the applicant and asserts that all pertinent arguments have been addressed in the previous office actions. Applicant states on page 5 of the remarks: " First, it is an oversimplification of the art analysis to suggest that a disclosed composition always necessary anticipates an identical claimed composition. The law is just plainly not so (see extensive briefing in a previous response). Whether we are talking about anticipation by inherency, or by some other means, there are many recognized cases, as discussed, where the previous disclosure of a composition for an use unrelated to a use now claimed for an 'identical' composition is not anticipatory, either inherently or otherwise." The examiner again points out that the applicant's claims are drawn to compositions and not to methods (or uses). Compositions are compositions regardless of their intended use.

The examiner respectfully points out the following: "Products of identical chemical composition can not have mutually exclusive properties. "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuznicki et al. (5,681 ,569).

Kuznicki et al. discloses a composition comprising 0.01-0.35% flavanols or catechins wherein the catechin or a mixture of two or more catechins are catechin, epicatechin, gallocatechin, epigallocatechin gallate and epicatechin gallate (see particularly col.3 lines 20-21 and 26-28), and a pharmaceutical carrier (i.e., water). See also abstract, col.2, lines12-14: Example 1, 11, and 111 at col.10, and claims 1 and 5-6.

Kuznicki et al. also discloses the composition therein is therapeutically useful in improving cognitive performance (see col.3 line 33 in particular). The therapeutic effective amount of a catechin or mixture of catechins, within the instant claim (1t-loomg/kg of body weight of the subject), is disclosed in the Example I and II (see col. 10 lines 1-41) as shown in the calculation below:

Example II discloses that a person can consume 835 cc (835 ml) of a beverage prepared according to Example I (see col.10 lines 40-41).

Since the water in the composition in Example I is 94.45%, the composition is aqueous solution. The density of water = 1 g/ml, thus the total amount of the composition in Example I is 835 g.

According to Example 1, the effective amount of catechins (or flavanols)

= 83% X 0.097% (see col.10 line 15 in particular) = 0.8099 g = 809.9 mg

OR in a different calculation, according to Example I (see particularly at col.10 lines 6 and 13-14)

the effective amount of catechins

= 835g X 0.35/100 X 29/100 = 0.8475 g = 847.5 mg.

Since a standard person weight is 70 kg, the range of effective amounts of catechins is 10 mg/kg X 70 kg =700 mg to 1000 mg/kg X 70 kg = 70,000 mg (700-70,000mg).

Thus, the effective amount of catechins as exemplified in Example I in the composition of Kuznicki et al., 809.9 mg or 847.5 mg, is within the instant claimed range.

Kuznicki et al. also discloses that catechins therein are extracted from green teas or other plants, and isolated from green tea by methods well known to those in the art (see particularly at col.4 lines 6-14). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin present in a plant, which is an inherent property of the composition of Kuznicki et al. Kuznicki et al. also discloses that catechins can be prepared by synthetic chemical method or commercially available (see col.4 lines 14-17).

Thus, Kuznicki's composition inherently treat amyloid in a mammal. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best* 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claims 17 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitsui (JP 10245342).

Mitsui discloses a pharmaceutical composition for diminishing the toxicity caused by β-amyloid protein comprising a catechin (or two or more catechins), such as epigallocatechin gallate and epicatechin gallate (see particularly page 1, 2nd paragraph, claims 1-3 at page 1., page 2 (0001), (0002)), and a pharmaceutical carrier (i.e., water). See also page 7 (0028), page 8 (0029).

In paragraphs 0027-0028 Mitsui discloses that tea polyphenol contains EGCg and ECg and that these can be extracted from tea leaves, separated and purified. Further the agent for use in the invention (catechin) can be used solely (anticipating claim 17) or mixed with auxiliary elements for regular use (anticipating claim 25). The agent can be administered by itself or with diluting agents or solvents such as water or alcohol or with diluents such as carboxymethyl cellulose.

In paragraph 0029, Mitsui discloses that the dosage of the agent can be determined based upon usage and even high dosages can be administered without worry of side effects as the compounds are highly safe.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19-24 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitsui as applied to claims 17 and 25 above, and further in view of Kuznicki.

Mitsui is as set forth above.

Mitsui does not teach administration of compounds in ranges from 10-100mg/kg or 10-1000mg/kg.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the dosages detailed by Kuznicki for Mitsui's agent as they are equivalent compounds, catechins are well tolerated with no significant side effects and Mitsui described that any tolerable effective dose is acceptable for treatment of β-amyloid toxicity. Further the determination of an effective dosage of a compound is within the realm of routine experimentation for one of ordinary.

The examiner respectfully points out the following from MPEP 2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-15 and 25-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 9-11 of the copending Application No. 10/762,444.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending Application is drawn to a drug product for treating amylodosis in a mammal comprising a composition a compound of Formula E which is epicatechin (see Fig. 1 B herein) and a pharmaceutically acceptable excipient. The claim of the instant application is drawn to a pharmaceutical composition for treating the same comprising (or consisting essentially of) epicatechin and pharmaceutically acceptable excipients in effective amounts within the copending Application claim.

Therefore, one of ordinary skill in the art would have found that the instant composition is clearly obvious in view of the copending Application No. 10/762,444.

Claims 9-15 and 25-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13'of the copending Application No. 10/610,349.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending Application is drawn to a pharmaceutical agent for treating amylodosis in a mammal comprising a composition a plant of the genus

Uncaria which is known as green teas. The claim of the instant application is drawn to a pharmaceutical composition for treating the same comprising (or consisting essentially of) epicatechin present in green teas and pharmaceutically acceptable excipients in effective amounts within the copending Application. Therefore, one of ordinary skill in the ad would have found that the instant composition is clearly obvious in view of the copending Application No. 10/610,349.

Claims 9-15 and 25-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of the copending Application No. 10/610,346.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending Application is drawn to a pharmaceutical agent for treating amylodosis in a mammal comprising a composition a plant of the genus Uncaria which is known to green teas. The claim of the instant application is drawn to a pharmaceutical composition for treating the same comprising epicatechin present in green teas and pharmaceutically acceptable excipients in effective amounts within the copending Application claim. Therefore, one of ordinary skill in the art would have found that the instant composition is clearly obvious in view of the copending Application No. 10/610,346.

Above obviousness-type double patenting rejections are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER